DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 20, 2013

Wuxi Jiajian Medical Instrument Co., Ltd.
c/o Ms. Doris Dong, Manager
Shanghai CV Technology Co., Ltd.
Room 1706, No. 128 Songle Rd.,
Songjiang Area
Shanghai 201600 China

Re: K123958
Trade/Device Name: Jiajian Pointoselect Digital
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: September 17, 2013
Received: September 25, 2013

Dear Ms. Dong:

This letter corrects our substantially equivalent letter of October 28, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use

510(k) Number (if known): K123958

Device Name: Jiajian® Pointoselect Digital

Indications for Use:

The Jiajian® Pointoselect Digital is intended for use in the symptomatic relief of chronic intractable pain, postoperative pain, and acute pain.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S

JIAJIAN®
佳健医疗

Section 5
510(k) Summary
[As required by 21 CFR 807.92]

OCT 2 8 2013

1. Submission Information:

510(k) Number:	K123958
Date:	March 13th, 2013
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd Qinghong Rd., Ehu Town, Xishan District, Wuxi, Jiangsu, China 214116
Contactor:	Doris Dong, Consultant Shanghai CV Technology Co., Ltd. Room 1706, No. 128 Songle Rd., Songjiang Area, Shanghai, China 201600 E-mail: doris_d@126.com / Url: www.ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-37824346

2. Device Description:

Proprietary Name:	Jiajian® Pointoselect Digital
Common Name:	Transcutaneous electrical nerve stimulator
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Regulation Number:	882.5890
Product Code:	GZJ
Device Class:	II
Review Panel:	Neurology
Indications for use:	Jiajian® Pointoselect Digital is intended for use in the symptomatic relief of chronic intractable pain, postoperative pain, and acute pain.
Device Description:	Jiajian® Pointoselect Digital is a newly designed and easy to operate hand held stimulator. It is 9V battery powered device, with an LCD in the console, which can display the selected operation mode, intensity, frequency, pulse width, and battery level of the device, and so on. The device composes of a console, a hand held probe, a hand grip electrode, and lead wires. The hand probe can be used for treatment at individual sites. When using the hand probe, the patient must hold the hand grip electrode in order to electrically ground the device.
Standards:	ISO 10993-5, ISO 10993-10; IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2

3. Predicate Device Identification

510k Number:	K060517
Product Code:	GZJ
Device Name:	Pointer Excel
Manufacturer:	LHASA OMS, INC.

4. Substantial Equivalence:

Detailed comparison data is included in the section of "Substantial Equivalence Discussion" of this 510(k) submission.

A. **Basic technological characteristics, New device VS. Predicate device:**

Parameters		New Device	Predicate Device
1.	510(k) Number:	K123958	K060517

2.	Marketing clearance date:	--	Jun 19th, 2006
3.	Device Name	Jiajian® Pointoselect Digital	Pointer Excel
4.	Manufacturer	Wuxi Jiajian Medical Instrument Co., Ltd	LIHASA OMS, INC.
5.	Accessories for stimulation mode	1 pcs. of hand probe for stimulation with lead wire; 1 pcs. of hand electrode with lead wire	1 pcs. of hand probe for stimulation; 1 pcs. of hand electrode with lead wire
6.	Intended use	Jiajian® Pointoselect Digital is intended for use in the symptomatic relief of chronic intractable pain, postoperative pain, and acute pain.	Pointer Excel is intended for use in the symptomatic relief of chronic intractable pain, postoperative pain, and acute pain.
7.	Power Source(s)	9 Volt battery type 6F22 (Carbon-zinc), or 9 Volt battery type 6LR61 (Alkaline)	DC 9V battery, Type 6F22
	- Method of Line Current Isolation	N/A for DC current	N/A for DC current
	- Patient Leakage Current - Normal Condition - Single Fault Condition	-- 20μA N/A	-- Not Stated in the manual Not Stated in the manual
8.	Number of Output Mode:	1	1
9.	Number of Output channels:	1	1
10.	Compliance with Voluntary Standards?	ISO 10993-5, ISO 10993-10; IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2	ISO 10993-5, ISO 10993-10; IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2
11.	Waveform	Biphasic	Biphasic
12.	Shape	Asymmetric biphasic square wave	Asymmetric biphasic square wave
13.	Maximum Output Voltage	6.6V ±15% @500Ω	11V±15% @500Ω
14.	Maximum Output Current	13.2mA ±15% @500Ω	22mA ±15% @500Ω
15.	Pulse Duration	60~120μS	220μS
16.	Frequency	2~18Hz	1~16Hz
17.	Net Charge	0μC @500Ω, + and – pulses cancel	0μC@500Ω
18.	Maximum Phase Charge	2.4μC@500Ω	4.8μC@500Ω
19.	Maximum Current Density (r.m.s.)	12.08mA/cm²@500Ω	10.35mA/cm²@500Ω
20.	Maximum Average Power Density	0.0036W/cm²@500Ω	0.0067W/cm²@500Ω

B. Substantial Equivalence Discussion

Similarities between New device and Predicate Device:	Intended use, DC power source, biphasic square waveform, Net charge, frequency range, maximum current density, maximum power density, adjustable frequencies and intensity, standards
Differences between New device and Predicate Device:	Weight, dimensions; Maximum output voltage, Maximum output current, Output pulse duration, Maximum phase charge
Conclusion:	The new device has same intended use, biphasic square waveform, complied standards, adjustable output intensity and frequency, and similar maximum output current density and power density. Though there are differences between the new devices and the predicate devices, such as output intensity values and pulse width, the differences would not raise new safety concerns. To sum up, the new device Jiajian® Pointoselect Digital is substantially equivalent to Predicate devices of Pointer excel (K060517).

5. Safety and Effectiveness of the device

Jiajian® Pointoselect Digital was tested and found to meet the safety standards of:

* IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995;
* IEC 60601-2-10 Edition 2.0 2012-06, Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators; and
* IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests

The pointer probe was tested and found to comply with the biocompatibility standards of:

* ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, and
* ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

The output lead wires used for Jiajian® Pointoselect Digital were tested and found to comply with the safety standards of:

* IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

The device was also tested basis on reduced battery level, and was found that the stimulus parameters were not significantly affected (less than ±10%).

The conclusion drawn from the testing is that the device is substantially equivalent to the predicate devices.